K121791

510(k) Summary

NOV 19 2012

Contact: Justin Eggleton
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Date Prepared: November 16, 2012

Device Trade Name: Zou® Anterior Lumbar Plate System

Manufacturer: CoreLink, LLC
10805 Sunset Office Drive, Suite 300
St. Louis, MO 63127

Common Name: Spinal Fixation Device

Classification: 21 CFR §888.3060; Spinal intervertebral fixation orthosis

Class: II

Product Code: KWQ

Indications For Use:

The CoreLink ZOU™ Anterior Lumbar Plate System is intended for use as an anteriorly placed supplemental fixation device via the lateral or anterior lateral surgical approach above the bifurcation of the great vessels or via the anterior surgical approach, below the bifurcation of the great vessels.

The CoreLink ZOU™ Anterior Lumbar Plate System is designed to provide temporary stability until fixation is achieved. It is intended for anterior lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Device Description:

The Zou® Anterior Lumbar Plate System is comprised of an assortment of titanium alloy plates and screws that act to stabilize the spine during the intervertebral fusion process. The Zou® Anterior Lumbar Plate System is manufactured from Ti-6Al-4V ELI in accordance with ASTM F136.

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Predicate Device(s):

The Zou® Anterior Lumbar Plate System was shown to be substantially equivalent to previously cleared devices and has the same indications for use, design, function, and materials used. These devices include the Spinal USA AccuFit Anterior Lumbar Plate System (K091044), Biomet Valiant Anterior Lumbar Plate System (K082187), Zimmer Trinica Anterior Lumbar Plate System (K061353), Synthes Anterior Tension Band System (K022791), and DePuy Aegis Anterior Lumbar Plate System (K052546).

Performance Standards:

Testing performed on this device indicates that the Zou® Anterior Lumbar Plate System is substantially equivalent to predicate devices. A modified ASTM F1717 test protocol was adhered to and all substantial equivalence requirements were met. This testing included static compression bending, static torsion, and dynamic compression bending.

Conclusion:

The Zou® Anterior Lumbar Plate System is substantially equivalent to predicate devices with respect to safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Corelink, LLC
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Justin Eggleton
Director, Spine Regulatory Affairs
1331 H Street, 12th Floor
Washington, District of Columbia 20005

Letter Dated: November 19, 2012

Re: K121791
Trade/Device Name: Zou® Anterior Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 31, 2012
Received: November 01, 2012

Dear Mr. Eggleton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121791

Indications for Use

510(k) Number (if known): K121791

Device Name: Zou® Anterior Lumbar Plate System

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number K121791